The Application of Reliability allocation methodology, from preliminary test data, to design a Definitive test plan. Application to Mechanical Heart Replacement Technology.

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The objective of this paper is to demonstrate the utility and relevance of the use of reliability allocation methodology in the design of reliability test plans for the qualification of new medical systems. This approach makes use of all of the information collected in the preliminary product development phases. Firstly, this methodology provides a resolution to optimizing the reliability allocation process for the design of a reliability test plan, with a view to cost containment and, secondly, demonstrates the applicability to the demanding constraints provided by the medical sector, and in particular, those in the field of Mechanical Heart Replacement Therapy. The Carmat Total Artificial Heart was the subject of this study, possibly the most demanding of reliability requirements, as it replaces the heart of patients with irreversible bi-ventricular heart failure and who are, consequently, totally reliable on the device for survival.

Keywords: Reliability allocation, System reliability, Medical device, Test plan, In-built test data, Reliability diagram.

1. Introduction

The intended use of the Carmat Total Articial Heart (C-TAH) is to provide long-term full circulatory support by replacing the heart of patients suffering from irreversible biventricular heart failure. The prosthesis encompasses two ventricular compartments, each separated by a membrane, into a blood compartment and a hydraulic compartment. The silicone hydraulic fluid is shuttled in and out of the compartments by two volumetric electro motor pumps, creating diastolic and systolic phases. The C-TAH system also has an external subsystem to provide support and to ensure patient autonomy.

The reliability specifications are very demanding since only minimal maintenance is possible and should be avoided as much as possible, from the time of implantation. This system differs from the more typical ventricular assist devices (VADs) due to its complexity which includes the synchronization of two ventricles and the associated actuating mechanisms. A sequence of test-x-test procedures brought about a series of technical improvements which provided preliminary functional test data. A reliability allocation was performed to address specific reliability goals to each of the components and subsystems, from the beginning. These were used as preliminary targets to shape the design elements. This enabled the global reliability target of the over-all system to be achieved. During the product development process, maturity of the different components increased as a consequence of the different changes implemented whilst striving to achieve the functional goals. Capitalization of this information was very important and gave some direction to the reliability allocation studies. At this stage, preliminary allocations were given to a system for which the technological choices were still developing but some reliability boundaries could be derived from the various components, based on these different functional tests. A limited number of tests on the components (usually one) and continuous changes in the overall design limited confidence, from a statistical point of view, to reliability estimates. Further tests need be conducted on critical components where the criticality is defined in terms of statistical goodness-of-fit and on the system for demonstrating reliability. It is also important to note that consideration should be given to cost containment in the chosen test modalities, given the potential expenses related to evaluating these complex innovative and specialized medical devices. It allows to optimize the sample size allocation and

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then improve the accuracy of reliability estimation from the test results.
Traditionally, accreditation authorities for medical systems recommend a demonstration of reliability which is only based on the simulation of real condition testing in which the device is exposed to clinically relevant loads and environments. Such a recommendation leads to very high costs and substantial delays in concluding the reliability demonstration tests, especially when time-to-market of innovative products needs to be expedited. The main objective of this paper is to extend and transfer some recent approaches in the demonstration of reliability, developed in different industrial sectors such as the automotive industry, to the medical domain.
The proposed methodology can be described as follows:

(1) The definition of an *a priori* reliability allocation using all of the information collected during the product development phase and the first proof-of-concept clinical trials. Cost considerations were included in the allocation methodology. This prior analysis leads to the identification of the critical com-ponents;
(2) The elaboration of the accelerated life time reliability test plans to the selected components;
(3) The construction of Bayesian system reliability demonstration test plans.

The C-TAH reliability evaluation was the purpose of this study, restricted in this paper to our specific allocation method, which also includes the test costs. The remainder of this paper is as follows; Section 2 is devoted to the presentation of the new reliability allocation method. In Section 3, the dissection of the C-TAH system is discussed with its associated dys-functional model and the application of the allocation method. A conclusion is proposed in Section 4.

2. Reliability allocation process

At the start of a system development program, a reliability allocation is made in order to allocate a reliability goal to each subsystem and component and then these are used as a requirement for the design of each element. This facilitates meeting the reliability goal of the final system. During the development process, the knowledge obtained, by analysis and development tests, enhances the maturity of components. The first allocation does not correspond to actual development. Furthermore, the test data collected provides a means to estimate reliability bounds, at a component level. This step then provides a basis for establishing a new reliability allocation which is necessary to provide a reliability target used in the reliability demonstration test.
The methods for allocating the reliability objectives attribute a weighting to each of the subsystems or components as a function of their failure rate.
The most well-known ARINC method (ARINC Research Corporation and Von Alven (1964)) is based on the experience gained from a previous system which serves as a reference for the design of the new system. This method is not suitable in the case of a new system, even if there are limits on the reliability of the components.
Other approaches as (AGREE (1957)), Karmiol method (Karmiol (1965)), the feasibility of objectives method (Anderson (1976)), the integrated factor method (Felice et al. (2001)) and recently the maximum entropy ordered weighted averaging method (Chang et al. (2009)) combine several criteria from system design (number of components, complexity, number of functions, state-of-the-art, criticality, operative profile) to obtain a reliability allocation weight. However, this method does not really assist in the management of improvements as a result of experience from data collection.
Several extensions have been proposed for solving some design issues in improvement efforts (Yadav and Zhuang (2014); Wu et al. (2018); Kim and Zuo (2018)) and in the analysis of the failure criticality over the reliability or safety objectives (Kim et al. (2013); Kim and Zuo (2018)).
Reliability objectives or any reliability parameter threshold has to be provided by the allocation method, with associated confidence levels, on each component, in a design test plan context. Finally, the validation test plan needs to be designed subject to these allocated confidence levels, which may, for example, dictate the sample size of each test as suggested by (Guo et al. (2014)).
Taking into account the above, a new reliability allocation method has been developed to include all of the available knowledge; the efforts for improvement and the testing costs. The new allocation method is based on:

- The reliability bounds estimation of each component,
- The system dysfunctional model,
- The costs of implementing the tests (based on test duration, the test benches, etc.) and of the components and the complete system.

The result provides reliability targets at subassembly level, which is defined in the system dissection, to design a reliability test plan.

2.1. *Probability allocation algorithm on elementary undesirable events*

The methodology allocates a failure rate target for each component of the system. This failure rate is assumed to be constant and consequently the estimated life-time is exponentially distributed.
The steps in the methodology are:

(1) Assign a weighting improvement factor to

each component based on *complexity*, *operational profile* and *severity*, with regard to risk analysis.
(2) Obtain a failure rate λ_i for each component i, based on the fault tree of top event and reliability allocation algorithm (1).
(3) Compute a failure probability goal p_i for each component i regards to reliability target on system ($p_i = 1 - e^{-\lambda_i \times T}$ with T corresponding to mission duration).

The allocation algorithm requires bounds of the failure rate of each component in order to yield a result. These intervals are the parameters of the optimization algorithm (the allocation algorithm is a constrained optimization algorithm).
The validation of the objective, in terms of the occurrence probability of the undesired event, should then be done. In principle, the failure rate of a single component can supersede the objective if such a failure results in a Top Event failure (case of the minimal cut sets of order 1 in the associated fault tree).

The Weighting Improvement Factor (WIF) is also input data for the allocation algorithm and provides a criterion for the possible improvement of the reliability of each of the components. WIF depends on four characteristics issue from Karmiol method (Karmiol (1965)): the component complexity, the component maturity level (characterized by the Technology Readiness Level) and the estimated impact severity relative to risk to the patient. The WIF is therefore a function of the sum of the above characteristics, normalized on a scale from 1 to 4. When this reliability allocation occurs at the end of a system design, the maturity level is not included and the WIF is consequently reduced to three characteristics; component complexity, mission profile and severity.

The inputs to the algorithm are:

- A probability goal with an associated confidence level,
- An interval on failure rate and a weighting factor for each component.

Notations:

P_O Probability goal of top level undesirable event occurring (for example, in case of risk analysis, it is the minimum acceptable frequency for an undesira-ble event).
P_S Current probability of top event.
IF Improvement ratio. It is equal to $max(\frac{\frac{1}{P_O}-\frac{1}{P_S}}{\frac{1}{P_O}}, \epsilon) = max(1-\frac{P_O}{P_S}, \epsilon)$.
Remark: As P_S is close to P_O, as the improvement factor is less and so the increment of failure rate is smooth.
ϵ minimum improvement ratio (for example, if $\epsilon = 0.1$, the evolution of λ can be as less as 10%.
λ_i^{min} minimal value of failure rate for ith component (best case).
λ_i^{max} maximal value of failure rate for ith component (worst case).
λ_i current value of failure rate for ith component.
λ_i^* modified failure rate for ith component with $\lambda_i^* = max(\frac{\lambda_i}{1+IF}, \lambda_i^{min})$
$P_{S\lambda_i^*}$ Probability of top event if the ith component is modified with failure rate λ_i^*.
WIF_i Weighting Improvement Factor for ith component (a value between 1 and 4 which corresponds to the difficulty to improve the reliability of a component). The default value is 1.
RG_i Relative Gain value for ith component.

The relative gain value for a component represent the ratio between the gain on reliability of system if the ith component is modified and the improvement effort to be done. The maximum value indicates the direction of the component where the improvement is the more efficient in terms of reliability. The absolute gain is the difference $P_{S\lambda_i^*} - P_S$. The improvement effort can be modeled by the mathematical model expressed by (Yadav and Zhuang (2014)):

$$E = \frac{ln(\lambda)}{r} + C$$

With

E improvement effort
r decreasing rate of λ
C a constant

This mathematical model express the well-establish belief that further improvement on a highly reliable component requires much more effort than less reliable component with the same level of improvement. Using this model, the improvement effort ΔE_i for a component i from λ_i to λ_i^* is:

$$\Delta E_i = \frac{ln(\lambda_i^*) - ln(\lambda_i)}{r_i}$$

The decreasing rate r_i is relative to WIF. We purpose here to express r_i as $r_i = 10^(1 - WIF_i)$.
Consequently, RG_i is

$$RG_i = \begin{cases} \frac{P_S - P_{S\lambda_i^*}}{(ln(\lambda_i^*) - ln(\lambda_i)) \times 10^{WIF_i - 1}} & if \lambda_i \neq \lambda_i^{min} \\ 0 & else \end{cases}$$

Algorithm iterations:

At beginning, each λ_i are initialize at λ_i^{max} value. On each step, the algorithm:

- Compute for each component i the relative gain value RG_i,
- For the component with the high relative gain value RG_i, the failure rate λ_i is modified by λ_i^*.

The criterion for ending the iteration is $P_S \leq P_O$. The steps in the allocation algorithm are described in the following Fig. 1.

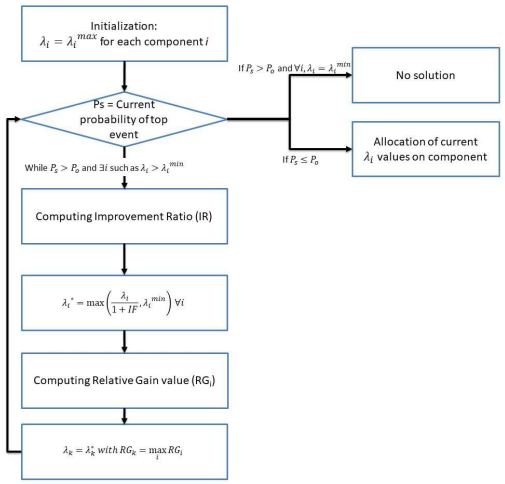

Fig. 1. Allocation algorithm scheme.

Calculation of probability goal on component:

The outputs of the algorithm are failure rate objectives λ_i for each component i on the mission duration. Hypothetically, the lifetime of components follows an exponential distribution. The probability goal for each component is $p_i = 1 - e^{(-\lambda_i \times T)}$ with T mission duration.

2.2. *Allocation of confidence level*

The failure probability objective at system level, P_O, has to be provided with a confidence level, $1 - \alpha_S$. α_S is the associated risk and represent the probability that the sample is accepted when it should be denied. The allocation method have to provide for each subsystem i included in the reliability test plan, a failure probability target p_i with an associated confidence level $1 - \alpha_i$ in order to validate the test at a subsystem approach.
The costs of tests in the allocation are taken into ac-count by assigning a weighting of C_i attributable to each component i to design the test plan such as $1 - \alpha_i = (1 - \alpha_S)^{C_i}$. C_i is the ratio of test cost from component i on the total test cost.

The confidence levels are set as:

$$1 - \alpha_S = \prod_i (1 - \alpha_i)$$

With

$1 - \alpha_S$ confidence level for complete system,
$1 - \alpha_i$ confidence level for subsystem i.

In fact, this allocation is conservative considering

$$\cap_i \{p_i \leq p_i^0\} \subset \{P_S \leq P_0\}$$

With

p_i probability of failure of subsystem i and p_i^0 associated reliability target,
P_S probability of failure of system and P_0 reliability target.

3. Application to Carmat TAH

3.1. *Decomposition of System and interfaces*

The complete system is divided into sub-assemblies that can be tested separately, in order to improve the reliability demonstration of each part. Fig. 2 presents the global organic architecture of the Carmat TAH with main subsystems and their principal functions. Nomenclature of this figure is in Table 1.

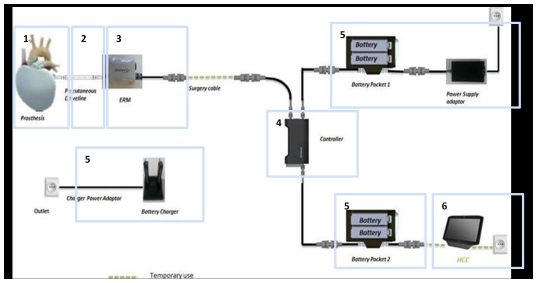

Fig. 2. Organic Architecture of C-TAH system.

Table 1. Nomenclature of Figure 2.

Index	Components
1	Prosthesis
2	Percutaneous driveline (CPP)
3	External Router Module (ERM)
4	Controller
5	Battery Pockets (BP)
6	Hospital Control Console (HCC)

This system is composed of external wearable and implantable parts. The system can be separated into three main subsystems:

- The prosthesis and percutaneous driveline - implantable
- ERM - external
- The wearable system - external

The Wearable subsystem is composed of four components, easily replaceable by the patient: Con-troller, Battery pockets, Power supply Adaptor, Battery charger. Additional components of the system include equipment bags, belts, hospital monitor and implant instruments, which are not part of this study.

Some remarks can be made:

- All implantable components (i.e. the prosthesis and percutaneous driveline) and the external ERM have to be included in the tests Lee (2009). From reliability estimation of ERM equipment, it is not necessary to carry out further tests on the equipment.ERM is integrated in the prosthesis tests.
- The wearable subsystem (Controller, Battery pockets, Power supply Adaptor, Battery charger) are evaluated separately, for practical reasons linked to in vitro test environment .

The test plan is therefore designed to incorporate the two subsystems:

- prosthesis, percutaneous driveline and ERM (called *prosthesis subsystem* for test purpose),
- Wearable subsystem.

3.2. *Dysfunctional model*

The aim of this section is to provide a fault tree with basic events, at component level, used in the reliability allocation algorithm. The primary function of a mechanical heart re-placement device is to provide the minimum acceptable, clinically relevant flow rate, based on the intended patient population Lee (2009). More generally, it constitutes the basal requirement of such a system. This reliability target corresponds to the ability of C-TAH to provide a minimal flow of 3.0 l/min, under all conditions, which is termed the *essential performance*.

Based on the results of risk analysis, a fault tree of the system is elaborated for the top undesirable event: loss of essential performances. To restrict the fault tree to *critical* (serious disability that could lead to death) and *catastrophic* (death) failures to the loss of essential performances, some components were excluded from the reliability demonstration:

- All software: reliability demonstration taken into account in software risk analysis,
- Components used temporary during implantation phase (HCC, extension cable implant accessory kit)
- Components not directly involved in essential performances endurance. These components were identified during risk analysis. For example, potentially, equipment used to hold on the system parts (belts, carry bag). Also, power supply adaptor and battery charger used temporary by patient.

All undesirable events from risk analysis that not lead to loose essential performances are not taking into account in this reliability demonstration. The fault tree is summarized to basic events of component/equipment failures as in Fig. 3.

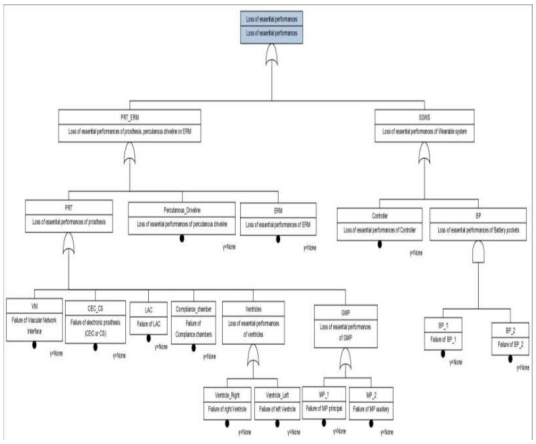

Fig. 3. Fault tree on loss of essential performances of C-TAH.

- The design of the prosthesis, percutaneous driveline and ERM does not include any redundant functions associated with essential performances. Consequently any failure of these components would lead to the loss of essential performances.
- No common mode failures between both battery pockets (BP_1 and BP_2) are identified to lead to loss of essential performances.

3.3. *Reliability target Allocation*

This failure rate is assumed to be constant and so the life-time is exponentially distributed. This assumption can be seen as restrictive but:

- Due to the uniqueness of this system, there is insufficient available background information is characterize the failure rate behavior.
- Considering that the period of infant mortality is avoided due to burn-in tests performed

on critical components (electronic and pumps) prior to incorporation into the system, a constant failure rate is conservative on mission duration. Indeed, for a time less than mission duration, the probability of failure is higher than considering an increase failure rate. Therefore, these evaluations represent a worst-case scenario.

The way to determine these factors is described in Table 2 below.

Table 2. Weight factors for the C-TAH.

Complexity	Explanations
1	The element is not complex and does not contain many components.
2	The element is not complex but contains many components.
3	The element is complex due to innovations without REX on reliability, but does not contain many components.
4	The element is complex due to physical constraints or innovations without REX on reliability, and contains many components.
Mission profile	**Description**
1	The equipment is not worn by the patient.
2	The equipment is worn by the patient.
4	The equipment is implanted in the patient.
Criticality	**Explanations**
1	The equipment failure does not lead to a critical failure.
2	The equipment is redundant but the associated function is classified as critical.
3	The equipment failure leads to a critical failure in the case of a degraded operating mode.
4	The equipment failure leads to a critical failure of system.

The input data for allocation algorithm are described in Table 3 and Table 4.

The weighting associated to test costs are respectively 0.72 and 0.28 for Prosthesis and the Wearable system. This results in test cost figures of approximately 5 for the prosthesis subsystem and approximately 2 for wearable system.

Results:

By application of reliability allocation algorithm in section 2.1, the results for each element are in Table 5.

Using the combination of the decomposition de-tail and the fault tree in Fig. 3, the refined reliability targets to the design test plan, for each subsystem, are contained in Table 6 below.

Table 3. Weight factor.

Element	Complexity factor	Profile factor	Criticality factor	Weight factor
ERM	1	2	4	2.33
BP_1	1	2	2	2
BP_2	2	2	2	2
Controller	4	2	4	3.33
CEC CS	4	4	4	4
CPP	1	4	4	3
Ventricle right	3	4	4	3.67
Ventricle left	3	4	4	3.67
main GMP	3	4	4	3.67
auxiliary GMP	3	4	4	3.67
Compliance chambers	4	4	4	4
LAC	1	4	4	3
VNI	2	4	4	3.33

Table 4. Lower and upper bound on failure rates.

Element	Minimum failure rate (h-1)	Maximum failure rate (h-1)
ERM	1.E-9	7.6938 E-5
BP_1	1.E-9	1.53 E-6
BP_2	1.E-9	1.53 E-6
Controller	1.E-9	5.01 E-6
CEC CS	1.E-9	2.35 E-5
CPP	1.E-9	7.6938 E-5
Ventricle right	1.E-9	8.7989 E-06
Ventricle left	1.E-9	8.7989 E-06
main GMP	1.E-9	2.1325 E-06
Auxiliary GMP	1.E-9	2.1325 E-06
Compliance chambers	1.E-9	1.0391 E-05
LAC	1.E-9	7.6938 E-5
VNI	1.E-9	7.6938 E-5

Table 5. Results on reliability allocation for elements.

Element	Failure probability allocation	Failure rate allocation (h-1)
ERM	5.35E-03	6.12E-07
BP_1	1.33E-02	1.53E-06
BP_2	1.33E-02	1.53E-06
Controller	1.68E-02	1.94E-06
CEC CS	3.59E-02	4.17E-06
CPP	1.15E-02	1.32E-06
Ventricle right	2.46E-02	2.84E-06
Ventricle left	2.46E-02	2.84E-06
main GMP	1.85E-02	2.14E-06
Auxiliary GMP	1.85E-02	2.14E-06
Compliance chambers	3.59E-02	4.18E-06
LAC	1.15E-02	1.32E-06
VNI	1.68E-02	1.94E-06

Table 6. Results on reliability allocation for design system test.

Subsystem	Reliability target	Associated confidence level
Prosthesis, Percutaneous driveline and ERM	0.8139	70%
Wearable system	0.9830	86%
Carmat TAH	0.8003	60%

4. Conclusion

Based on the requirements for the industrial application of long-term circulatory support, we propose a methodology to allocate reliability goals to each system component with an associated confidence level. This approach offers an improvement over tradition-al methods of reliability allocation takings into ac-count the reliability bounds established from preliminary product development reliability testing and ap-plying a weighting on improvement efforts aimed at increasing reliability. A weighting related to test costs, is also applied to define the confidence level of each of the subsystems. Finally, the results provide reliability goals for each subsystem to formulate a design test plan.

As an example, we provide the application of this approach, using real data from long-term circulatory support provided, by the Carmat Company. Having designed a test plan for each sub-system, the confidence level for the complete system can be re-fined using methodologies described in P Zeiler and B Bertsche (2015) or Guo et al. (2014). Once the test conditions and possible test plan are frozen, this type of methodology can be used to enhance accurate confidence levels on demonstrated reliability.

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